

## REMARKS

### *1. Status of claims*

Claims 82-102 and 125 are pending and under consideration.

### *2. Objections to the claims*

The Examiner objected to claims 84-90, 92-93, and 95 as allegedly being unclear for reciting a "portion" of nucleus pulposus tissue. Applicants respectfully traverse this objection.

At p. 12, line 24 to p. 14, line 2, the present specification discusses decellularization, denaturation, degradation, extraction, and crosslinking. The cited passage identifies portions of nucleus pulposus tissue that can be decellularized (p. 12, line 31 to p. 13, line 1), denatured (p. 13, lines 1-2), degraded (p. 13, lines 2-3), extracted (p. 13, lines 3-5), and crosslinked (p. 13, lines 20-22). Therefore, Applicants submit the "portions" recited in claims 84-90, 92-93, and 95 are clear and request this objection be withdrawn.

### *3. Claim rejections under 35 U.S.C. § 103(a)*

The Examiner rejected claims 82-88 and 91-102 as being unpatentable over Mechanic, US 5,854,397 ("Mechanic") in view of Gan, *et al.*, US 5,964,807 ("Gan"). Applicants respectfully traverse this rejection.

The Examiner alleges Mechanic teaches a process for crosslinking proteinaceous material and Gan teaches a hybrid material comprising intervertebral disc cells and a biodegradable support substrate, wherein the intervertebral disc cells are nucleus pulposus cells which may be obtained from the patient or from donor tissue. The Examiner further alleges the person of

ordinary skill in the art would then find it obvious to use the hybrid material of Gan in the process of Mechanic, which would then allegedly produce the method recited by the present claims.

Mechanic fails generally to teach a method of manufacturing an intervertebral disc implant and, as noted by the Examiner, specifically “does not teach nucleus pulposus tissue.” Gan fails to remedy these deficiencies as it teaches away from the use of donor nucleus pulposus tissue. Although Gan notes “tissue may be extracted from the nucleus pulposus of lumbar discs, sacral discs and cervical discs,” that tissue subsequently is discarded to obtain isolated nucleus pulposus cells. These isolated cells are then combined with materials intended to substitute for the discarded nucleus pulposus tissue from which they were isolated. Throughout the specification, Gan repeatedly emphasizes the mechanical and chemical destruction of the nucleus pulposus tissue to liberate cells for use in creating a hybrid matrix. As such, a person of skill in the art would have no reason to combine Gan with Mechanic to achieve the claimed invention.

Therefore, Applicants submit claims 82-88 and 91-102 are patentable over Mechanic in view of Gan and request this rejection be withdrawn.

Second, the Examiner rejected claims 89-90 as being unpatentable over Mechanic in view of Gan and further in view of Moore, *et al.*, US 6,350,732 (“Moore”). The Examiner alleges Moore teaches a method for extracting lipids from a collagenous tissue sample. Applicants respectfully traverse this rejection.

Mechanic and Gan have been discussed above with respect to independent claim 82 and claims dependent thereon. As a threshold matter, claims 89-90, which also depend on claim 82 are patentable for at least the reasons noted above. In addition, Moore, like Mechanic, fails to teach “nucleus pulposus tissue” and does nothing to remedy the deficiencies of Gan in this regard.

As such, the teachings of Moore with those of Mechanic and Gan would not lead the person of ordinary skill in the art to the presently claimed invention.

Therefore, Applicants submit claims 89-90 are patentable over Mechanic in view of Gan and Moore and request this rejection be withdrawn.

4. *Conclusion*

Applicants submit all pending claims are in condition for allowance. The Examiner is invited to contact the undersigned patent agent at (713) 934-4065 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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